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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,006	06/14/2001	Yoji Sakagami	026350-058	4690

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EXAMINER
KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	11

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/880,006	SAKAGAMI ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 2-11,13,14,16,17,19 and 20 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,12,15,18 and 21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1, 12, 15, 18, and 21 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that there would be no undue burden in examining Groups I-V together, and that up to ten sequences are permitted per MPEP 803.04. This is not found persuasive because sequences of Groups I-V are drawn to unique DNA compositions of discreet length and function. The prior indication, in 1996, that up to ten sequences were permissible was meant to apply to EST sequences, rather than promoters or coding sequences. Furthermore, since 1996 resources at the Patent office have changed, and the examination and search of more than one sequence would pose an undue burden. Finally, one sequence constitutes "up to ten".

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 12, 15, 18, and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims the promoter sequence from the rice *PSK* gene of SEQ ID NO: 1; parts of SEQ ID NO: 1 wherein a base sequence of unspecified sequence and length is added, deleted, or substituted; and an unspecified base sequence that hybridizes with SEQ ID NO: 1 under unspecified stringent hybridization conditions.

Applicant describes SEQ ID NO: 1 (-3359 to -1), and fragments of SEQ ID NO: 1; SEQ ID NO: 2 (-1911 to –1), SEQ ID NO: 3 (-1034 to –1), SEQ ID NO: 4 (-563 to –1) on pages 2-4; sequences -148 to –1 of SEQ ID NO: 1, -3359 to -1034 of SEQ ID NO: 1, and -1911 to –1034 of SEQ ID NO: 1 on page 13 lines 8-21; and SEQ ID NO: 5 (-3359 to -2033) comprising the promoter of SEQ ID NO: 1 and the gene encoding phytosulfokine precursor from rice on page 4.

Applicant does not describe any other fragments, deletion, additions or substitutions to SEQ ID NO: 1 (-3359 to -1), other than fragments of SEQ ID NO: 1; SEQ ID NO: 2 (-1911 to –1), SEQ ID NO: 3 (-1034 to –1), SEQ ID NO: 4 (-563 to –1), on pages 2-4; sequences -148 to –1 of SEQ ID NO: 1, -3359 to -1034 of SEQ ID NO: 1, and -1911 to –1034 of SEQ ID NO: 1 on page 13 lines 8-21; and SEQ ID NO: 5 (-3359 to -2033) comprising the promoter of SEQ ID NO: 1 and the gene encoding phytosulfokine precursor from rice on page 4. Applicant also does not describe any promoter from any non-rice source or non-PSK gene which would hybridize under conditions of low or moderate stringency to SEQ ID NO: 1.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the

actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Given the failure of the various promoter DNA sequences of SEQ ID NO: 1 to be adequately described, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-111.

4. Claims 1, 12, 15, 18, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter of SEQ ID NO: 1 and promoter fragments of SEQ ID NO: 1 (-1911 to –1, -1034 to –1, -563 to –1, -148 to –1, -3359 to –1034, and -1911 to –1034) driving GUS expression in rice cells transformed with said fragments, does not reasonably provide enablement for all of the claimed promoter fragments or parts of SEQ ID NO: 1 comprising parts either substituted for, added to, deleted from said sequence, sequences hybridizing under unspecified stringent conditions, and a method of activating expression in plant cells other than rice or any plants transformed with said promoter or promoter fragments by incorporation upstream of an exogenous or endogenous structural gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims active promoter sequences comprising the promoter of rice PSK gene of SEQ ID NO: 1; active parts of SEQ ID NO: 1 wherein a base sequence of unspecified sequence and length is added, deleted, or substituted; an active promoter of unspecified base sequence that hybridizes with SEQ ID NO: 1 under unspecified stringent hybridization conditions; and a method of activating an endogenous or exogenous gene by incorporation of the promoter upstream of said structural gene.

Applicant teaches the promoter of SEQ ID NO: 1 and promoter fragments of SEQ ID NO: 1 (-1911 to –1 in pIG121-4, -1034 to –1 in pIG121-3, -563 to –1 in pIG121-2, -148 to –1 in pIG121-1, -3359 to –1 with -3359 to –1034 in reverse orientation in pIG121-7, and –1911 to –1 with -1911 to –1034) in reverse orientation in pIG121-5, driving GUS expression in rice cells transformed with said fragments; and pIG121 as GUS positive control (page 12 lines 10-12, page 13 lines 8-21, and figure 6).

Applicant does not teach activation of any exogenous gene, other than GUS, in any plant cells or plant body, using any active parts of SEQ ID NO: 1 or any active parts wherein a base sequence of unspecified sequence and length is added, deleted, or substituted; or any active promoter of unspecified base sequence that hybridizes with SEQ ID NO: 1 under unspecified stringent hybridization conditions other than SEQ ID NO: 1 and promoter fragments of SEQ ID NO: 1 (-1911 to –1 in pIG121-4, -1034 to –1 in pIG121-3, -563 to –1 in pIG121-2, -148 to –1 in pIG121-1, -3359 to –1 with -3359 to –1034 in reverse orientation in pIG121-7, and –1911 to –1 with -1911 to –1034 in reverse orientation in pIG121-5); or the activation of any endogenous gene in any plant cells or any plant body transformed using any active parts of SEQ ID NO: 1 or any active parts wherein a base sequence of unspecified sequence and length is added, deleted, or

substituted; or any active promoter of unspecified base sequence that hybridizes with SEQ ID NO: 1 under unspecified stringent hybridization conditions.

Isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al. (1999, Plant Molecular Biology Vol. 40: pp. 857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2^{nd} paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

The state of the art for modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable. The specific effects of given promoters on gene expression in transformed plants of different species can not be anticipated with any reasonable degree of predictability and one of skill in the art must rely upon an empirical determination (Benfey *et al.*, Science 250:959-966, 1990, see Abstract, lines 14-18 and column 1, page 966, lines 29-45).

Moreover, transforming with a homologous inter-functional 5' UTR regulatory gene sequence, which is unpredictable, is exemplified in the loss of heritable activity of a target gene regulated by a promoter inserted into a genome already containing a homologous endogenous

copy of that promoter, and cannot be anticipated with any reasonable degree of predictability (Park Y. D. *et al.,* Plant Journal 1996, Feb. 9, (2): 183-194, see Abstract).

Given the lack of guidance for isolating parts of sulphokine promoters or modifying sulphokine promoters from a myriad of species that would retain activity when transformed into any one of a number of plant species and tissue specific types of plant cells, the limited working examples in the specification, the breadth of the claims, and the unpredictability in the art, undue trail and error experimentation would have been required by one skilled in the art to isolate evaluate a multitude of non-exemplified forward or reverse promoter sequences or parts thereof in a myriad of non-exemplified plant cells and non-exemplified plants and plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 12, 15, 18, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

At Claim 1, lines 4 and 5, "a part of" is indefinite. It is unclear what part of the sequence is to be affected.

At Claim 1, line 8, "stringent conditions" is indefinite. It is not clear whether conditions of low, moderate, or high stringency are to be used.

At Claims 15 and 18, lines 2 and 3 of each claim, "a structural gene existing downstream of the promoter" is indefinite. Since the claims do not depend upon claim 12 it is unclear whether

the claimed promoter was operably linked to either said endogenous or exogenous structural gene prior to transformation.

At Claim 21, the entire claim, "exogenous structural gene" or "endogenous structural gene" is indefinite. Since the claim does not depend upon claim 12 it is unclear whether the claimed promoter was operably linked to either said endogenous or exogenous structural gene prior to transformation. Furthermore, "into upstream of" in line 3 is awkward.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Even though the promoter sequence itself is narrowly defined ("consisting of") it is not isolated, part (a) reads on a native plant containing the promoter of SEQ ID NO: 1. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang H. *et al.* GenBank Accession Number AB026837 submitted April 28, 1999.

Yang teaches a gene encoding a phytosulfokine precursor isolated from a genomic library comprising SEQ ID NO: 1 sequences –3359 to –1 corresponding to upstream region of the isolated genomic clone, sequences 1 to 3359, inherently a promoter region. The genomic clone is inherently contained in a plasmid. Thus the reference teaches all of the limitations of Claims 1 and 12.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 12, 15, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang H. *et al.* GenBank Accession Number AB026837 submitted April 28, 1999 in view of Christensen A. *et al.* Transgenic Research, 1996, Vol. 5 pp. 213-218.

Applicant broadly claims claims active promoter sequences comprising the promoter of rice PSK gene of SEQ ID NO: 1; active parts of SEQ ID NO: 1 wherein a base sequence of unspecified sequence and length is added, deleted, or substituted; an active promoter of unspecified base sequence that hybridizes with SEQ ID NO: 1 under unspecified stringent

hybridization conditions; and a method of activating an endogenous or exogenous gene by incorporation of the promoter upstream of said structural gene.

The teachings of Yang are discussed supra.

Yang does not teach the expression of the promoter region of the isolated gene in a transgenic plant.

Christensen teaches expression of selectable and scorable markers using the *ubi-1* promoter from maize to transform different monocot species. (see Abstract and page 213 column 2 to page 214 column 1, line 2).

It would have been obvious at the time of Applicant's invention to modify the invention of Yang to include a plasmid and a method for activating expression of exogenous or endogenous genes by plant transformation using the promoter region of the phytosulfokine precursor gene from rice. One of skill in the art would have been motivated by the knowledge common in the art that the promoter regions of plant genes are valuable materials for genetic engineering of plants and the success of Christensen in enhancing the expression of endogenous and exogenous genes, and that one would have had a reasonable expectation of success of expressing genes in transformed plants and plant cells.

11. All claims are rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

Russell Kallis Ph.D.
November 26, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638